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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,149	02/19/2004	Ghassan S. Kassab	P01568-US-01 (26259.0010)	5030
22446	7590	04/09/2008	EXAMINER	
ICE MILLER LLP ONE AMERICAN SQUARE, SUITE 3100 INDIANAPOLIS, IN 46282-0200			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/782,149	<b>Applicant(s)</b> KASSAB ET AL.	
	<b>Examiner</b> Brian Szmaj	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-41 and 59-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-34 is/are allowed.
- 6) ☒ Claim(s) 22-30, 35-41 and 59-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 and 07 January 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 66 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly amended claim discloses a method for measuring a cross sectional area of a treatment site by injecting a first and second solution at the site and calculating the cross sectional area based on the measured conductances of the solutions, and inflating the balloon and measuring the cross sectional area based on the conductance inside the balloon. The current specification is silent with regards to measuring the cross sectional area using two methods at the same time.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 22-24, 29, 30, 35, 36 and 59-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krivitski (EP 1025805 A1) in view of Krivitski (5,453,576).

Krivitski ('805) discloses a means for determining blood flow during the treatment of vascular occlusions and further discloses introducing an impedance catheter into the treatment site; providing a constant electrical current flow to the treatment site through the catheter; injecting a known volume of a first solution of a first compound having a first conductivity into the treatment site; measuring a first conductance value at the treatment site; injecting a second solution into the treatment site; measuring a second conductance value at a treatment site; calculating the cross-sectional area of the treatment site based on the first and second conductance values and the conductivities of the first and second compounds; the treatment site includes a body lumen; the body lumen comprises a blood vessel; the first and second compounds are NaCl; the catheter comprises an inflatable balloon along the longitudinal axis of the catheter; inflating the balloon to break up any materials causing the stenosis at the treatment site; injecting the first solution local to the treatment site; injecting the second solution local to the treatment site; and the injected first and second solutions temporarily substantially displaces the blood at the treatment site. See Paragraphs 0012, 0018, 0020, 0034-0036, 0048, 0052, 0054, 0059; and Figure 3.

Krivitski ('805) however fails to disclose the first and second solutions differ with respect to the conductivities of the solutions; and the first and second solutions are heated to body temperature or a common temperature prior to injection.

Krivitski ('576) discloses a means for measuring cardiovascular functions and further discloses the first and second solutions differ with respect to the conductivities of the solutions; and the first and second solutions are heated to body temperature or a common temperature prior to injection. See Column 16, lines 52-66; and Column 17, lines 1-5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Krivitski ('805) to include the use of two different NaCl solutions, as per the teachings of Krivitski ('576), since it would provide a means comparing the conductivity measurements between the two solutions in order to obtain a more accurate cross-sectional area measurement. It also would have been obvious to one of ordinary skill in the art to utilize an equal volume of the first and second solutions since it would provide a standard measure of the two solutions while only differing in conductivity.

5. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Krivitski (EP 1025805 A1) and Krivitski (5,453,576) as applied to claim 23 above, and further in view of Lafontaine et al (5,665,103).

Krivitski ('805) and ('576), as discussed above, disclose means for measuring the cross-sectional area of a lumen, but fail to disclose the body lumen comprises a biliary tract.

Lafontaine et al disclose a stent locating catheter and further disclose the placement of the device in the biliary tract. See Column 3, lines 11-14.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Krivitski ('805) and Krivitski ('576) to have the ability to place the catheter at a location in the biliary tract, as per the teachings of Lafontaine et al, since it is well known in the art to provide devices that have the ability to traverse body lumens, including the patient's vasculature as well as other lumens such as the esophagus and biliary tract.

6. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krivitski (EP 1025805 A1) and Krivitski (5,453,576) as applied to claim 23 above, and further in view of Mabary et al (2004/0254495 A1).

Krivitski ('805) and ('576), as discussed above, disclose means for measuring the cross-sectional area of a lumen, but fail to disclose the lumen comprises the esophagus; the injecting the first and second solution comprises administering the solutions orally.

Mabary et al disclose a means for measuring esophageal function and further disclose the lumen comprises the esophagus; the injecting the first and second solution comprises administering the solutions orally. See Paragraphs 0024, 0031 and 0038.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Krivitski ('805) and Krivitski ('576) to include the ability to obtain measurements in the esophagus, as per the teachings of Mabary et al, since the esophagus is another body lumen that a catheter can be placed within to obtain measurements.

7. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krivitski (EP 1025805 A1) and Krivitski (5,453,576) as applied to claim 35 above, and further in view of Boneau (2002/0049488 A1).

Krivitski ('805) and ('576), as discussed above, disclose means for measuring the cross-sectional area of a lumen, but fail to disclose a stent located over the balloon, the stent is capable of being placed at the treatment site; distending the stent by inflating the balloon; releasing and implanting the stent at the treatment site; selecting the stent for the treatment site; and implanting the stent at the treatment site.

Boneau discloses a stent and a means for implanting a stent and further discloses a stent located over the balloon, the stent is capable of being placed at the treatment site; distending the stent by inflating the balloon; releasing and implanting the stent at the treatment site; selecting the stent for the treatment site; and implanting the stent at the treatment site. See Paragraphs 0010, 0014, 0034, 0037, 0039 and 0042.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Krivitski ('805) and Krivitski ('576) to include the ability to implant a stent at the treatment site, as per the teachings of Boneau, since it is well known to utilize a balloon catheter to implant a stent at a treatment site.

8. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krivitski (EP 1025805 A1) and Krivitski (5,453,576) as applied to claim 22 above, and further in view of Shalman et al (6,471,656 B1).

Krivitski ('805) and ('576), as discussed above, disclose means for measuring the cross-sectional area of a lumen, but fail to disclose a pressure sensor; measuring a first pressure gradient from the pressure transducer; and calculating the cross-sectional area of the treatment site based in part on the pressure gradient value.

Shalman et al disclose a means of obtaining pressure based measurements of a body lumen and further disclose a pressure sensor; measuring a first pressure gradient from the pressure transducer; and calculating the cross-sectional area of the treatment site based in part on the pressure gradient value. See Column 29, lines 14-62.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Krivitski ('805) and Krivitski ('576) to include the use of a pressure sensor and measuring the cross-sectional area based on the pressure measurement, as per the teachings of Shalman et al since it would provide an additional means of measuring the cross-sectional area of the body lumen.

### ***Allowable Subject Matter***

9. The following is a statement of reasons for the indication of allowable subject matter: Claims 31-34 are allowed since no prior art could be found teaching or suggesting selecting a catheter for introduction into the treatment site based on the measurement of a first conductance and a first current density at the site.

### ***Response to Arguments***



10. Applicant's arguments filed January 7, 2008 have been fully considered but they are not persuasive.

11. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., measuring the instantaneous cross-sectional area) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Krivitski ('805) and Krivitski ('576) disclose the use of injecting two separate injections of a saline solution. Both Krivitski ('805) and Krivitski ('576) provide the support for one of ordinary skill in the art to inject two different saline solutions in order to obtain the currently claimed method.

The Applicants then argue the means of Krivitski ('805) would be rendered inoperable with the combination of Krivitski ('576). The Examiner respectfully disagrees. Krivitski ('805) clearly discloses the use of two injections of a saline solution, but is

clearly silent with respect to the concentrations of the saline solutions. Since Krivitski ('805) is silent with respect to the saline concentrations, one of ordinary skill in the art would be able to arrive at the conclusion that the injected boluses do not have to be the same concentration. Krivitski ('576) discloses the use of two different saline concentration boluses. Therefore, one of ordinary skill in the art would have been able to combine Krivitski ('805) with Krivitski ('576) in order to obtain the current claimed method with a reasonable amount of success.

### ***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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